UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE, INCORPORATED,

Plaintiff,

vs.

VYSIS, INC.,

Defendant.

CASE NO. 99-CV-2668 H (AJB)

Order Denying Motion for Stay and for Dismissal of Fourth Cause of Action

On January 25, 2000, the plaintiff, Gen-Probe Incorporated ("Gen-Probe") filed a first amended complaint for declaratory relief and unfair competition relating to a patent and license agreement with the defendant Vysis, Incorporated ("Vysis"). On March 9, 2000, Vysis filed a motion to stay proceedings and for dismissal of the cause of action for unfair competition. Gen-Probe filed their opposition on April 10, 2000, and Vysis filed their reply on April 17, 2000. The motion was submitted on the papers and no oral argument was held.

BACKGROUND

Gen-Probe is a biotechnology firm which develops and continues to develop diagnostic tests called genetic probes or nucleic acid tests ("NAT"). (First Am. Compl. ¶ 6-7). Gen-probe allegedly patented a certain nucleic acid technology known as "Transcription-Mediated Amplification" which enables its products to detect "extraordinarily small quantities of the nucleic acids of infectious agents." (Id. ¶ 9). In early of 1999, Vysis informed Gen-Probe that it believed that Gen-Probe's HIV and HCV blood screening products infringed claims of their United States Patent No. 5,750,338 ("'338 patent")

(Id. ¶ 20). The '338 patent allegedly concerns probes for polynucleotide molecules such as DNA and RNA. (Id. ¶ 20).

In order to avoid any complications concerning the planned sale of its NAT test kits, Gen-Probe entered into a license agreement with Vysis concerning the '338 patent. (Id.). Under the terms of this agreement, Gen-Probe must make financial payments to Vysis for royalties of the sale of any products covered by the '338 patent. (Id. ¶ 21).

Gen-Probe now alleges that the '338 claims are invalid and that their NAT tests would not infringe on the '338 patent if the claims were valid. In its complaint, Gen-Probe asserts the following causes of action: (1) non-infringement of the '338 patent; (2) invalidity of the '338 patent; (3) declaratory relief concerning the licensing agreement between the parties; and (4) a state court unfair competition claim under California Business and Professions Code section 17200, *et seq.*

DISCUSSION

I. Request for Stay

Vysis argues that the matter should be stayed pending a reissue application of the '338 patent with the United States Patent and Trademark Office ("PTO"). In considering a motion for stay, a Court must weigh the benefits resulting from the reissue process against the hardships and prejudice that a stay will cause on the parties. See Xerox v. 3Com Corp., 69 F. Supp. 2d 404, 406-07 (W.D.N.Y. 1999).

In this matter, Gen-Probe contends that the '338 patent is invalid. Vysis asserts that because the PTO will consider the reissue application in light of Gen-Probe's assertions that the patent is invalid, a stay would further "interests of judicial economy" and the Court would benefit from the PTO's expertise and conclusions concerning the reissue application. However, the validity of a patent cannot be based solely on the decisions of the PTO and the Court must still rule on the validity of the patent. See Quad Environmental Tech v. Union Sanitary Dist., 946 F.2d 870, 875 (Fed. Cir. 1991) (holding that courts are the final arbiters of patent validity and must decide without deference to the rulings of the patent examiner).

Furthermore, there is no way to determine the length of time required for the PTO to examine the reissue patent application. The parties disagree on whether the expedited status of reissue

applications would guarantee its resolution within a year and the PTO's procedures concerning the examination of the application are beyond the Court's control.

Consequently, the Court DENIES the request for a stay at this time.

II. Motion to Dismiss the Cause of Action for Unfair Competition

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Vysis also moves to dismiss the fourth cause of action for unfair competition under California Business and Professions Code section 17200, *et seq.* To prevail on this claim, Vysis must show that "the plaintiff can prove no set of facts in support of [its] claim that would entitle [it] to relief." See Schneider v. California Department of Corrections, 151 F.3d 1194, 1996 (9th Cir. 1998). Furthermore, the Court must accept the facts that Gen-Probe asserts in its complaint as true. See Cooper v. Pickett, 137 F.3d 616, 623 (9th Cir. 1997). Section 17200 proscribes unlawful, unfair or fraudulent business practices or conduct. See Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co., 20 Cal.4th 163, 180 (1999).

Gen-Probe alleges that Vysis "knows or should know the underlying facts establishing the validity of the . . . '338 patent." (First Am. Compl. ¶ 35). Gen-Probe also alleges that Vysis continues to attempt to enforce this patent despite its knowledge that the patent is invalid. (Id.). The Court finds that these allegations sufficiently allege a cause of action under Federal Rule of Civil Procedure 12(b)(6). Consequently, the motion to dismiss is DENIED.

CONCLUSION

The Court DENIES the motion for a stay. The Court also DENIES the motion to dismiss the fourth cause of action.

IT IS SO ORDERED.

DATED: 4/28/00

MARILYN L. HUFF, CHIEF JUDGE
UNITED STATES DISTRICT COURT

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TAB 1

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The Collins patent is directed to an amplification process for amplifying a target polynucleotide contained in a sample, comprising the steps of contacting the sample with a first support which binds to the target polynucleotide; substantially separating the support and bound target polynucleotide from the sample; and amplifying the target polynucleotide. The term "amplify" is defined very broadly in the specification. This definition is broad enough to include, for example, amplification of captured polynucleotides by cloning; production of cell-free translation products of the captured polynucleotides; and the enzymatic reproduction of the captured polynucleotide.

Numerous prior art references disclose binding of polynucleotides to solid supports, separating the support and the bound polynucleotides from the sample and subsequently amplifying the polynucleotides by insertion into cloning vectors and growing up in host cells. As merely illustrative of such papers, one can mention *Arsenyan, S.G. et al., Gene 11:97-108 (1980).* Other references disclose binding polynucleotides to solid supports, separating the support and bound polynucleotides from the sample and amplifying the polynucleotides by using them to produce translation products in cell-free translation systems. See, for example, *Strair, R.K. et al, P.N.A.S. 74:4346-4350 (1977)* and *Hirsch, F.W. et al, P.N.A.S. 75:1736-1739 (1978).* Note also that the Strair reference describes the use of a "retrievable support" for capture of the polynucleotide. Still other references disclose binding of polynucleotides to solid supports, separating the support and bound polynucleotides from the sample and amplifying the polynucleotides enzymatically. These include *Montgomery, D.L. et al, J. Biol. Chem., 257:7756-7761(1982)* and *Boss, J.M. et al, J. Biol. Chem., 256:12958-12961 (1981).* Again, note that the Boss reference discloses a dispersible support. I would also draw your attention to *Georgiev, G.P. et al, Science, 195:394-397 (1977),* which discloses "the preliminary enrichment [by capture on a solid support] of DNA used for amplification".

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